K090745
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JUN 18 2009

SECTION 5

510(K) SUMMARY

FOR
SIEMENS ARTIS ZEE / ZEEGO FAMILY VC14

Submitted by:
Siemens AG, Healthcare Sector, USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

March 17, 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Contact Person:**
Mr. Gary Johnson
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Siemens AG, Healthcare Sector, USA, Inc
51 Valley Stream Parkway E-50
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2. **Device Name and Classification**

Product Name:	Artis zee and Artis zeego - Modular Angiographic System
Classification Name:	Angiographic X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1600
Device Class:	Class II
Product Code:	90 IZI

3. **Intended Use:**

Artis zee / zeego is a family of dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients.

Procedures that can be performed with the Artis zee / zeego family include cardiac angiography, neuro-angiography, general angiography, rotational angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures as well as procedures next to the table for i.e. patient extremities.

Additional procedures that can be performed include angiography in the operating room, image guided surgery by X-ray, by image fusion, and by navigation systems. The examination table as an integrated part of the system can be used for X-ray imaging, surgery and interventions

Artis zee / zeego can also support the acquisition of position triggered imaging for spatial data synthesis.

The intended use and indications for use of the Artis **zee / zeego** VC14 have minor changes from its predicate device the Artis **zee / zeego** VC13, K073290

4. **Device Description:**
The Artis **zee / zeego** Modular Angiography System is designed as a set of components that may be combined into different configurations to provide specialized angiography systems. For these models, a new SW version VC14 will be available. The new SW version VC14 will allow additional functionality of currently used applications and is extended with new features (i.e. a wide screen display, a new OR table, and laser light crosshair). SW VC14 also includes an extension of the intended use to surgical angiography, including general surgical use for patients in the OR.
The Artis **zee / zeego** Modular Angiography System with SW VC14 is substantially equivalent to the AXIOM Artis Modular Angiography System VC13 with all its components as described in the Device Description, Section 11 and the Substantial Equivalence Section 12.

5. **Substantial Equivalence:**
The Artis zee / zeego Modular Angiography System SW VC14 is a modification of a legally marketed device and substantial equivalent to Artis zee, Artis zeego SW VC13 as listed below.

510(k) Number	Date of Clearance	Device Name
K073290	February 11th, 2008	Artis zee, Artis zeego Angiographic X-ray Systems

A detailed Substantial Equivalence Comparison is provided in Section 12.

6. **Summary of Technological Characteristics of the Principal Device as compared with the Predicate Device:**
Artis **zee / zeego** Modular Angiography System is designed as a set of components (C-arm, X-ray tube and housing, flat detector, digital imaging system, collimator, generator etc.) that may be combined into different configurations to provide specialized angiography systems. Many of the components used with Artis **zee / zeego** are either commercially available with current Siemens systems or include minor modifications to existing components. New or modified features provided with Artis zee/zeego SW VC 14 are provided in the Executive Summary as well as in the Device Description.

7. **General Safety and Effectiveness Concerns**:

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features including visual and audible warnings are incorporated into the system design. In addition the Artis **zee / zeego** Modular Angiography System is continually monitored, and if an error occurs, the system functions will be blocked and an error message will be displayed.

Furthermore the operators are health care professionals familiar with and responsible for the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

Performance Data:

Applicable testing was performed to evaluate the modifications to the Artis **zee / zeego** family. The test results were found to be acceptable as required by the respective test plans and protocols.

Conclusion:

The testing reported in this 510(k) establishes the device is safe and effective for its intended use and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2009

Mr. Gary Johnson
Technical Specialist, Regulatory Affairs, Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
MALVERN PA 19355

Re: K090745
Trade/Device Name: Artis zee / zeego
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI
Dated: June 5, 2009
Received: June 9, 2009

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4

Indications For Use

510(k) Number (if known): K090745
Device Name: Artis zee / zeego

Indications for Use:

Artis zee / zeego is a family of dedicated angiography systems developed for single and biplane diagnostic imaging and interventional procedures including, but not limited to, pediatric and obese patients.
Procedures that can be performed with the Artis zee / zeego family include cardiac angiography, neuro-angiography, general angiography, rotational angiography, multipurpose angiography and whole body radiographic/fluoroscopic procedures as well as procedures next to the table for i.e. patient extremities.
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Artis zee / zeego can also support the acquisition of position triggered imaging for spatial data synthesis.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090745